

**Amendments to the Claims:**

This listing of claims will replace all prior versions, and listings of claims in the application:

**Listing of Claims:**

1                   1.       (Currently amended): A method for managing stability studies, the  
2   method comprising:  
3                    displaying, on at least one display device, one or more first interfaces that enable  
4   a user to create stability studies by specifying requirements that need to be fulfilled for the  
5   stability studies;  
6                    receiving input via the one or more first interfaces indicative of a set of  
7   requirements for a first stability study;  
8                    displaying, on the at least one display device, one or more second interfaces that  
9   enable a user to create workflows associated with stages of stability studies, a workflow  
10   including information configured to prompt a user to perform one or more actions that need to be  
11   taken during a stage associated with a stability study in order to fulfill requirements specified for  
12   the stability study;  
13                   receiving input via the one or more second interfaces indicative of a set of  
14   workflows associated with a plurality of stages of the first stability study, each workflow  
15   specifying a set of actions that need to be taken during each stage in the plurality of stages of the  
16   first stability study;  
17                   displaying, on the at least one display device, one or more third interfaces that  
18   enable a user to specify business rules for stability studies;  
19                   receiving input via the one or more third interfaces indicative of a set of business  
20   rules for the first stability study;  
21                   generating one or more fourth interfaces for the first stability study with a data  
22   processing device based on the set of requirements that need to be fulfilled for the first stability  
23   study, the set of workflows associated with the plurality of stages of the first stability study, and

the set of business rules, wherein the one or more fourth interfaces define the set of requirements for the stability study;  
displaying, on the at least one display device, the one or more fourth interfaces;  
receiving input information via the one or more fourth interfaces, the received input information for fulfilling the requirements; and  
validating the received input information using the data processing device against the set of business rules for the stability study to determine whether the input information is acceptable.

2. (Currently amended): The method of claim 1, further comprising if the input information is acceptable, storing the input information using a storage device.

3. (Currently amended): The method of claim 1, further comprising:  
determining whether the set of requirements for the first stability study have been completed; and  
if the set of requirements have not been completed, outputting, on the at least one display device, one or more fifth interfaces requesting additional input information for the requirements in the set of requirements that have not been completed.

4. (Previously presented): The method of claim 1, further comprising:  
determining whether approval from a user is needed for the input information based on the set of workflows.

5. (Currently amended): The method of claim 4, further comprising:  
receiving an indication of approval from the user; and  
storing the indication using a storage device.

6. (Original): The method of claim 5, wherein the indication comprises at least one of an electronic signature and captured signature.

7. (Currently amended): The method of claim 4, further comprising:

2 receiving an indication from the user of disapproval;  
3 determining requirements that need to be completed for approval; and  
4 outputting, on the at least one display device, one or more fifth interfaces defining  
5 the determined requirements that need to be completed for approval.

1 8. (Previously presented): The method of claim 1, wherein the one or more  
2 second interfaces include an interface for a stage in the plurality of stages in the first stability  
3 study.

1 9. (Original): The method of claim 8, wherein the plurality of stages  
2 comprise at least two of a stability study setup criteria, stability study planning criteria, initial  
3 sampling and testing criteria, stability study launch criteria, stability study testing criteria, and  
4 stability study evaluation criteria.

1 10. (Currently amended): The method of claim 1, further comprising  
2 outputting, on the at least one display device, information summarizing the first stability study.

1 11. (Previously presented): The method of claim 1, further comprising  
2 determining a result of the first stability study.

1 12. (Original): The method of claim 11, wherein the result is inputted by a  
2 user.

13.-26. (Canceled).

1 27. (Previously presented): A tangible computer readable medium storing a  
2 set of instructions for managing a stability study when executed by a processor of a data  
3 processing system, the computer readable medium comprising:  
4 code for displaying one or more first interfaces that enable a user to create  
5 stability studies by specifying requirements that need to be fulfilled for the stability studies;  
6 code for receiving input via the one or more first interfaces indicative of a set of  
7 requirements for a first stability study;

code for displaying one or more second interfaces that enable a user to create workflows associated with stages of stability studies, a workflow including information configure to prompt a user to perform one or more actions that need to be taken during a stage associated with a stability study in order to fulfill requirements specified for the stability study;

code for receiving input via the one or more second interfaces indicative of a set of workflows associated with a plurality of stages of the first stability study, each workflow specifying a set of actions that need to be taken during for each stage in the plurality of stages of the first stability study;

code for displaying one or more third interfaces that enable a user to specify a set of business rules for stability studies;

code for receiving input via the one or more third interfaces indicative of a set of business rules for the stability study;

code for generating one or more fourth interfaces for the first stability study based on the set of requirements that need to be fulfilled for the first stability study, the set of workflows associated with the plurality of stages of the first stability study, and the set of business rules, wherein the one or more fourth interfaces define the set of requirements for the stability study;

code for displaying the one or more fourth interfaces;

code for receiving input information via the one or more fourth interfaces, the received input information for fulfilling the requirements; and

code for validating the received input information against the set of business rules for the stability study to determine whether the input information is acceptable.

28. (Previously presented): The computer readable medium of claim 27, further comprising code for storing the input information when the input information is acceptable.

29. (Previously presented): The computer readable medium of claim 27, further comprising:

code for determining whether the set of requirements for the first stability study have been completed; and

code for outputting one or more fifth interfaces when the set of requirements have not been completed that request additional input information for the requirements in the set of requirements that have not been completed.

30. (Previously presented): The computer readable medium of claim 27, further comprising:

code for determining whether approval from a user is needed for the input information based on the set of workflows.

31. (Previously presented): The computer readable medium of claim 31, further comprising:

code for receiving an indication of approval from the user; and  
code for storing the indication.

32. (Previously presented): The computer readable medium of claim 31, wherein the indication comprises at least one of an electronic signature and captured signature.

33. (Previously presented): The computer readable medium of claim 30, further comprising:

code for receiving an indication from the user of disapproval;  
code for determining requirements that need to be completed for approval; and  
code for outputting one or more fifth interfaces defining the determined requirements that need to be completed for approval.

34. (Currently amended): A system for managing stability studies, the system comprising:

a first interface configured to enable a user to create stability studies by specifying requirements that need to be fulfilled for stability studies, workflows associated with stages of stability studies, and business rules for stability studies;

6 a database configured to store information associated with the requirements, the  
7 workflows, and the business rules for stability studies, wherein a workflow includes information  
8 configured to prompt a user to perform one or more actions that need to be taken during a stage  
9 ~~associated~~ associated with a stability study in order to fulfill requirements specified for the  
10 stability study;

11 a stage selector configured to select a stage of a stability study and to determine  
12 from the database one or more requirements for the selected stage;

13 a stage information manager configured to receive the one or more requirements  
14 from the stage selector, to generate a second interface that defines the one or more requirements  
15 for the selected stage that need to be fulfilled, and to generate a third interface indicative of  
16 information on actions associated with the selected stage that need to be performed;

17 a stage information processor configured to receive input via the second and third  
18 interfaces and to validate the input against business rules associated with the selected stage to  
19 determine whether the input is acceptable.

1 35. (Previously presented): The system of claim 34 wherein the first interface  
2 is further configured to enable the user to create a specification for a first stability study as an  
3 overlay using a specification for a second stability study as a base.